

**IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF OHIO  
EASTERN DIVISION**

**CLARK TIBBS,**

**Plaintiff,**

**v.**

**KATHLEEN SEBELIUS, et. al.,**

**Defendants.**

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**Case No: 2:09-cv-773**

**JUDGE MARBLEY**

**MAGISTRATE JUDGE ABLE**

**OPINION AND ORDER**

**I. INTRODUCTION**

This matter is before the Court on Defendants Nancy J. Cox, Anthony Fauci, Bruce Gellin, Barney Graham, Nicole Lurie, Kathleen Sebelius, and the National Institutes of Health's ("Defendants") Motion to Dismiss pursuant to Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6) (Dkt. 22). Defendants bring their motion to dismiss Plaintiff Clark Tibbs' ("Tibbs") Complaint (Dkt. 2), filed on September 3, 2009. For the reasons stated below, Defendants' Motion to Dismiss is **GRANTED**, and Tibbs' Motion for Leave to File Amended Complaint (Dkt. 25) is **DENIED**.

**II. BACKGROUND**

Plaintiff, Clark Tibbs, is a resident of Newark, Ohio, and works for PhageVax, a corporation with its principal place of business in Newark, Ohio. Tibbs alleges that Defendants have placed him at an increased risk of contracting a potentially deadly infectious disease, namely the H1N1 virus (also known as the "Swine Flu"), due to Defendants' negligence and failure to carry out properly their non-discretionary, statutory duties under 42 U.S.C. §§ 241,

247d-6b(a), 247d-7e(b)(1) and (c)(2), 300aa-2(a). These statutes give the Secretary of Health and Human Services authority to perform research and investigations (42 U.S.C. §§ 241); maintain a strategic national stockpile of drugs, vaccines, and other biological products (42 U.S.C. § 247d-6b(a)); establish the Biomedical Advanced Research and Development Authority within HHS (42 U.S.C. § 247d-7e(b)(1) and (c)(2)); and provide that the Director of the National Vaccine Program shall coordinate and provide direction for vaccine research and development (42 U.S.C. § 300aa-2(a)).

The following facts about H1N1 are taken from Tibbs' Complaint, and for the purposes of this Motion to Dismiss, are assumed to be true.

Seasonal influenza is an infectious disease that has annual winter outbreaks throughout the world. On June 11, 2009, the World Health Organization declared a pandemic due to a novel H1N1 virus, which is twice as infectious as the typical seasonal influenza virus. On August 24, 2009, a United States Presidential Advisory Panel made the following predictions about H1N1: 1) between 30-50% of the United States population was at risk to be infected with H1N1; 2) up to 90,000 United States citizens may die from H1N1 infections; 3) H1N1 would contribute to enormous stress on intensive care units in hospitals; and 4) a resurgence of H1N1 might occur in September 2009, but the H1N1 vaccine would not be available until the middle of October 2009.

There is a global shortage of manufacturing capacity for influenza vaccines, such that there is a dangerous shortage of vaccines to immunize the population of the United States against H1N1 and to combat a pandemic influenza strain. The Advisory Committee on Immunization Practices recommended the following priority groups to be targeted for vaccination: pregnant

women, health care and emergency services personnel, children, adolescents and young adults, household and caregiver contacts of children younger than six months, and healthy adults with certain medical conditions. Tibbs is a healthy, middle-aged male, and is not a member of one of the priority groups, and therefore may not receive a H1N1 vaccination.

Tibbs alleges that the shortage of influenza vaccine because the vaccines are produced using an egg-based technology, which make it difficult to cultivate the quantities of virus necessary and takes four months after identification of the influenza strain to produce doses tailored to the new strain. Despite Defendants' knowledge of the slow and ineffective egg-based technologies, they continue to financially support and depend on this technology, and do not engage in substantial efforts to develop and test new vaccine technologies, in violation of the statutory duties outlined above.<sup>1</sup> Finally, Tibbs' alleges that it was foreseeable to the Defendants that the lack of preparedness and failure to find new vaccine technologies has resulted in placing the lives of United States citizens, including Tibbs, in imminent harm of contracting the H1N1 virus.

### **III. STANDARD OF REVIEW**

Defendants' bring their Motion to Dismiss pursuant to Fed. R. Civ. P. 12(b)(1) and 12(b)(6).

When a defendant argues that the plaintiff has not alleged sufficient facts in the

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<sup>1</sup>Tibbs, under the name PhageVax, developed a new method of creating a vaccine for H1N1 using bacteriophage and *E. coli* bacteria. The Complaint contains numerous allegations related to PhageVax's attempts to receive funding from Defendants to continue testing and developing this new vaccine. PhageVax has been voluntarily dismissed from this action, therefore this Court does not relate the facts regarding PhageVax.

complaint to establish subject matter jurisdiction pursuant to Federal Rule of Civil Procedure 12(b)(1), the court takes the allegations in the complaint as true. *Nichols v. Muskingum College*, 318 F.3d 674, 677 (6th Cir.2003). The plaintiff bears the burden of proving jurisdiction. *DLX, Inc. v. Kentucky*, 381 F.3d 511, 516 (6th Cir.2004); *Moir v. Greater Cleveland Reg'l Transit Auth.*, 895 F.2d 266, 269 (6th Cir.1990); *Rogers v. Stratton Indus.*, 798 F.2d 913, 915 (6th Cir.1986). “[M]otions to dismiss for lack of subject matter jurisdiction fall into two general categories: facial attacks and factual attacks.” *United States v. Ritchie*, 15 F.3d 592, 598 (6th Cir.1994). A facial attack challenges the sufficiency of a complaint, and, when considering the motion, the court must view the material allegations in the complaint as true and construe them in the light most favorable to the nonmoving party. *Id.* A factual attack is a challenge to the factual existence of subject matter jurisdiction. *Id.* In a factual attack “the court may consider evidence outside the pleadings to resolve factual disputes concerning jurisdiction, and both parties are free to supplement the record by affidavits.” *Nichols*, 318 at 677. In this case, given the arguments made in Defendants’ Motions to Dismiss, the Court will treat Defendants’ Motion as a facial attack.

A case may be dismissed if the complaint does not state a claim on which relief can be granted. Fed. R. Civ. P. 12(b)(6). “A motion to dismiss for failure to state a claim is a test of the plaintiff’s cause of action as stated in the complaint, not a challenge to the plaintiff’s factual allegations.” *Golden v. City of Columbus*, 404 F.3d 950, 958-59 (6th Cir. 2005). Consequently, the Court must construe the complaint in the light most favorable to the non-moving party, accept all factual allegations as true, and make reasonable inferences in favor of the non-moving party. *Total Benefits Planning Agency, Inc. v. Anthem Blue Cross & Blue Shield*, 552 F.3d 430,

434 (6th Cir. 2008); *Murphy v. Sofamor Danek Gp., Inc.*, 123 F.3d 394, 400 (6th Cir. 1997).

However, the Court is not required to accept as true mere legal conclusions unsupported by factual allegations. *Ashcroft v. Iqbal*, 129 S.Ct. 1937, 1949 (2009) (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 555, 127 S. Ct. 1955 (2007)).

Although liberal, the Rule 12(b)(6) standard requires more than the bare assertion of legal conclusions to survive a motion to dismiss. *Allard v. Weitzman*, 991 F.2d 1236, 1240 (6th Cir. 1993) (citation omitted). The complaint must “‘give the defendant fair notice of what the claim is, and the grounds upon which it rests.’” *Nader v. Blackwell*, 545 F.3d 459, 470 (6th Cir. 2008) (quoting *Erickson v. Pardus*, 551 U.S. 89, 127 S.Ct. 2197, 2200 (2007)). While a complaint need not contain “detailed factual allegations,” its “[f]actual allegations must be enough to raise a right to relief above the speculative level.” *Twombly*, 550 U.S. 544, 127 S. Ct. 1955, 1964 (2007). A complaint that suggests “the mere possibility of misconduct” is insufficient; rather, the complaint must state “a plausible claim for relief.” *Iqbal*, 129 S.Ct. at 1950 (citing *Twombly*, 550 U.S. at 556).

#### IV. LAW AND ANALYSIS

##### A. Counts to Which Tibbs Does Not Contest Dismissal

In his response to Defendants’ Motion to Dismiss, Tibbs consents to the dismissal of Counts VI, VII, and VIII. Accordingly, Counts VI, VII, and VIII are **DISMISSED**.

##### B. Standing

It is well settled that in order for a federal court to have jurisdiction over an action, the plaintiff must establish standing, as standing is a core component of the case-or-controversy requirement of Article III of the United States Constitution. *Lujan v. Defenders of Wildlife*, 504

U.S. 555, 560-61 (1992). There are three elements in order for a plaintiff to establish standing: 1) an injury-in-fact that is a) concrete and particularized (the injury must affect the plaintiff in a personal and individual way), and b) actual or imminent, not conjectural or hypothetical; 2) a casual connection between the injury and the conduct complained of; and 3) it must be likely that the injury will be redressed by a favorable decision. *Id.* (internal citations omitted). Finally, it is the party invoking federal jurisdiction that bears the burden of establishing standing, as the standing requirements “are not mere pleading requirements but rather an indispensable part of the plaintiff’s case.” *Id.* at 561; *Airline Prof’l Ass’n of Int’l. Broth. of Teamsters, Local Union No. 1224, AFL-CIO v. Airborne, Inc.*, 332 F.3d 983, 987-89 (6th Cir. 2003) (upholding the district court’s dismissal where plaintiff was unable to meet burden of establishing an injury-in-fact and therefore lacked Article III standing). On a motion to dismiss, however, “general factual allegations of injury resulting from the defendant’s conduct may suffice, for on a motion to dismiss we presum[e] that general allegations embrace those specific facts that are necessary to support the claim.” *Id.* (internal citations omitted); *Sutton v. St. Jude Medical S.C., Inc.*, 419 F.3d 568, 575 (6<sup>th</sup> Cir. 2005) (finding that where the plaintiff “alleges an increased risk of harm when comparing those individuals implanted with the device to those undergoing traditional surgery. Accepting Sutton’s allegations as true, the standing requirements have been met.”).

In determining whether a plaintiff has alleged an injury-in-fact, the Sixth Circuit has held that an “[i]njury-in-fact means that the plaintiff has sustained or is in immediate danger of sustaining some direct injury. The injury must be both real and immediate, not conjectural or hypothetical.” *Airline Pro’l Ass’n*, 332 F.3d at 987 (internal citations omitted). Although a conjectural or hypothetical injury is not sufficient to establish standing, the Sixth Circuit has

found that an increased risk of future harm may be sufficient as an injury-in-fact. *Sutton*, 419 F.3d at 575. Even where there is an future harm, however, a plaintiff is required to establish that the injury-in-fact is concrete and particularized, meaning that it must affect the plaintiff in a personal and individual way. *American Civil Liberties Union v. Nat'l Sec. Agency*, 493 F.3d 644, 660 (6<sup>th</sup> Cir. 2007) (citing *Steel Co. v. Citizens for a Better Env't*, 423 U.S. 83, 108 (1998); *Kardules v. City of Columbus*, 95 F.3d 1335, 1347 (6<sup>th</sup> Cir. 1996)). A generally available grievance about the government is not enough to establish an injury-in-fact to confer individual standing. *Joelson v. U.S.*, 86 F.3d 1413, 1423 (6<sup>th</sup> Cir. 1996). Where “the harm at issue is not only widely shared, but is also of an abstract and indefinite nature,” a court is unlikely to find that a plaintiff has established an injury-in-fact for standing purposes. *Fed. Election Comm’n v. Akins*, 524 U.S. 11, 23 (1998).

In this case, Defendants bring their Motion to Dismiss for Counts I-V based on Tibbs’ failure to establish standing, and in particular, an injury-in-fact. Tibbs’ alleged injury is future harm from the increased risk of contracting a potentially deadly infection disease – the H1N1 virus – because of Defendants’ failure to carry out their statutory duties. Defendants’ argue that Tibbs has failed to allege a sufficiently concrete and particularized injury-in-fact. This Court agrees. Construing all of the alleged facts in Tibbs favor, he is simply unable to show a concrete and particularized harm that affects him in a personal and individualized way. Even in *Baur v. Veneman*, 352 F.3d 625, (2<sup>nd</sup> Cir. 2003), the case on which Tibbs principally relies, the Second Circuit noted that:

we need not decide as a matter of law whether enhanced risk generally qualifies as sufficient injury to confer standing, *nor do we purport to imply that we would adopt such a broad view*. In the specific context of food and drug safety suits, however, we conclude that such injuries are cognizable for standing purposes,

where the plaintiff alleges exposure to potentially harmful products.  
*Id.* at 634 (emphasis added).

Furthermore, in *Sutton*, the only Sixth Circuit case upon which Tibbs relies, the court found an injury-in-fact for a future injury where the plaintiff, who had not suffered any injury, already had a device implanted in his heart that had resulted in severe complications for other patients with the same implant. 419 F.3d at 575. There are no such facts in this case. Tibbs has not alleged that he has been exposed to harmful products, as in *Baur*, or that he is particularly at risk for contracting the H1N1 virus, as in *Sutton*. Rather, Tibbs' injury is a generalized grievance about the manner in which a government agency is carrying out its statutory mandate. While Tibbs is correct in his assertion that a wide-spread injury is not enough to defeat standing, *see Fed. Election Comm'n v. Akins*, 542 U.S. 11, 24 (1998), the injury he alleges is not just widespread,<sup>2</sup> but also fails to allege a concrete and particularized harm – as it rests solely on the possibility of exposure *and* contraction of the H1N1 virus. Although Tibbs' Complaint contains detailed information about the serious and deadly scientific nature of the H1N1 virus, these facts do not lead to the finding of an injury-in-fact caused by the Defendants. This Court finds, therefore, that it does not have jurisdiction as Tibbs has not established an injury-in-fact and cannot establish standing. Without an injury, the remaining prongs of standing, causation and redressability, need not be addressed.

Accordingly, Counts I-V of Tibbs' Complaint are **DISMISSED**.

### **C. Freedom of Information Act**

Having dismissed Counts I-VIII, the sole remaining count in Tibbs' action is Count IX,

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<sup>2</sup> In fact, Mr. Tibbs injury is so widespread that it affects every person residing in the United States and its territories.



“Violation of the FOIA By HHS and Ms. Sebelius.” The Freedom of Information Act (“FOIA”) only grants jurisdiction to district courts to enjoin agencies from withholding records. 5 U.S.C. §522(a)(4)(B). Under the statute, this Court does not have jurisdiction over Ms. Sebelius for a FOIA claim, and HHS is not party to this action. This Court, therefore, does not have jurisdiction and Count IX must be dismissed.<sup>3</sup>

## V. CONCLUSION

Accordingly, and for the reasons stated above, Defendants’ Motion to Dismiss is **GRANTED** (Dkt. 22) pursuant to Federal Rule of Procedure 12(b)(1). Tibbs’ Motion for Leave to File Amended Complaint is **DENIED** (Dkt. 25). This case is **DISMISSED**.

**IT IS SO ORDERED.**

s/Algenon L. Marbley  
**ALGENON L. MARBLEY**  
**United States District Court Judge**

**DATED: April 30, 2010**

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<sup>3</sup> Even if this Court were to grant Tibbs’ Motion for Leave to File Amended Complaint, the Court would continue to lack jurisdiction because FOIA “requires exhaustion of the appeal process before seeking relief in the courts. Failure to exhaust all administrative remedies will result in dismissal of an action for lack of subject matter jurisdiction.” *Percy Squire Co., LLC, et al., v. The Federal Communications Commission*, No. 2:09cv428, 2009 WL 2448011, \*4 (S.D. Ohio, Aug. 7, 2009). While courts do recognize constructive exhaustion, “once the agency responds to the FOIA request, the requester must exhaust his administrative remedies before seeking judicial review.” *Id.* (citing *Oglesby v. United States Dep’t of Army*, 920 F.2d 57, 63-64 (D.C. Cir. 1990)). Defendants state that HHS responded Tibbs’ request on December 4, 2009 and notified him that the documents he requested were withheld pursuant to FOIA exemptions. If HHS were a party to this action, this Court would not have jurisdiction unless Tibbs had exhausted his administrative remedies by appealing the HHS decision.

Tibbs further argues that exhaustion is not required because Count IX is not an action based on failure to respond to a FOIA request, but rather that HHS promulgated a rule that violates its duty under FOIA. No duty arises under FOIA, however, until a request for documents is received by an agency. 5 U.S.C. § 552(a)(3)(A).